REMARKS

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed February 14, 2012. Applicants respectfully traverse (and do not concede) all objections, rejections, and adverse assertions made by the Examiner. Claims 22, 24-28, and 30-37 remain pending, with claims 31-34 and 36 previously withdrawn. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 22, 24-26, 28, and 30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. (U.S. Patent No. 4,610,665) in view of Picha et al. (U.S. Patent No. 5,080,654), and Kranys (U.S. Patent No. 5,207,656). Applicants respectfully traverse the rejection.

Independent claim 22 recites:

> 22. A catheter having a vacuum seal, comprising:
> an elongate catheter shaft having a proximal end, a distal end, a guidewire lumen defined therethrough, and an inflation lumen defined therethrough;
> a balloon disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen;
> a port disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen and a flanged end; and
> a seal member releasably attached to the flanged end and covering the opening;
> wherein the seal member does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen.

None of Matsumoto et al., Picha et al. or Kranys, taken alone or in combination, appear to teach or suggest a releasable seal member that does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen.

Matsumoto et al. appear to disclose a medical device including a valve body. The valve body appears to be configured to allow an additional medical device, such as a rod-like member, to pass through the valve body into the medical device. The valve body appears to include two slits crossing perpendicular to each other. When the additional medical device is not inserted into the medical device, the slits appear to maintain a substantially fluid tight seal. The slits appear to allow the additional medical device to pass through the valve body while still maintaining a fluid tight seal. Once the additional medical device has been removed, the slits

appear to close and again provide a substantially fluid tight seal. As acknowledged by the Examiner, Matsumoto et al. do not appear to teach or suggest a seal having a solid cross-section or a releasable seal. In formulating the rejection, the Examiner appears to rely on Picha et al. as disclosing a releasable seal and Kranys as disclosing a seal member that does not include a preformed opening.

Kranys appears to disclose a partition member that may be aperture free. It appears that the partition member may be formed from a foamed elastomer material having either an open cell or closed cell structure. In formulating the rejection, the Examiner asserts

> Kranys additionally discloses the seal may alternatively comprise a solid cross section initially with no pre-formed opening (Fig 3). In this second embodiment, a piercing member passes through the seal (24a) to form a slit that exactly fits the transverse dimensions of the piercing member inserted therethrough (col 4, II 1-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Matsumoto such that the pre-formed slits (17/18) were replaced with a seal member having a self-sealing solid cross-section.

Applicants respectfully disagree. Matsumoto et al. disclose at column 2, lines 20-28:

> The present invention has as its object the provision of a medical instrument having a valve body having hollow rod-like members including hollow cylindrical members and/or solid columnar members <u>of widely varied outer diameters inserted therethrough and held therein in a liquid-tight state</u>, capable of immediately forming a proper closed state when the rod-like member or members are withdrawn, and having a simple construction.

Emphasis added. Matsumoto et al. appear to disclose the object of the invention is to allow a number of different members of widely varied outer diameters to be inserted through a valve body and be held within the valve body in a liquid-tight state. Applicants respectfully assert that if one of ordinary skill in the art were to form a slit that exactly fits the dimensions of one particular member of Matsumoto et al., the device would not function as intended. For example, it appears that is one were to first desire a large diameter member to be placed through the valve, one would be required to make a large slit to accommodate the large diameter member. If one were to desire a smaller diameter member to be placed through the valve, a large slit would already be present. Applicants respectfully assert that the advancement of a small diameter member through a large slit would not appear to maintain a liquid-tight state as required by Matsumoto et al. MPEP 2143.01 V states, "If proposed modification would render the prior art

invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)."

In formulating the rejection, the Examiner further asserts, "[s]uch a modification would further ensure fluid cannot pass through the seal unintentionally. Furthermore, it has been shown a seal with pre-formed slits and a seal with an initial solid cross section without a pre-formed opening are functional equivalents." Applicants respectfully disagree. Applicants respectfully assert that a seal with pre-formed slits and a seal with an initially solid cross-section are not functional equivalents in every situation as the Examiner appears to be asserts. Applicants respectfully assert that in at least the scenario set forth above, the two are not functional equivalents.

Moreover, none of Matsumoto et al., Picha et al. or Kranys appear to teach or suggest the seal is "is self-sealing such that the seal maintains a vacuum within the inflation lumen" as recited n claim 22. In formulating the rejection, the Examiner asserts in reference to Matsumoto et al., "Since the seal is self-sealing to "thereby form a reliable liquid-tight or air-tight state between the catheter 15 and the valve body 16" (col6, ll 4-5) upon withdrawal of a piercing member inserted therethrough, the seal member is capable of maintaining a vacuum with the inflation lumen." Applicants respectfully assert that Matsumoto et al. only appear to disclose the seal maintains an air-tight state when the catheter is inserted through the valve member. If the Examiner is asserting that the valve member must inherently maintain a vacuum. Applicants respectfully disagree. Applicants respectfully assert the valve member may maintain a liquid seal without necessarily being capable of maintaining a vacuum. In accordance with M.P.E.P. §2112(IV) the Examiner must provide rationale or evidence tending to show inherency. The section states, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Moreover, Applicants submit that a reference being silent regarding a structure cannot be deemed to positively teach that structure.

Furthermore, while Kranys appears to disclose a partition member that is aperture free, Kranys does not appear to teach or suggest a seal that is capable of maintaining a vacuum. Kranys appears to disclose that due to the cellular nature of the foam, some fluid and/or air may pass through the partition member. For example, at column 2, lines 17-22 Kranys discloses, "An

advantage of open cell foams is that they tend to be more compliant than closed cell foams, since the air in the cells can migrate to other cells as a probe passes through the partition member, stretching and expanding the member." Kranys further discloses at column 2, lines 41-45, "Also, closed cell foams provide an improvement in sealing, in that blood cannot migrate through the microstructure of the closed cell foams since there is no flow path, while with open cell foams, some blood migration might take place this way." As can be seen, Kranys appear to disclose that at least with open cell foams, some blood migration through the partition member may be expected. Furthermore, with respect to closed cell foams, it appears that once an aperture has been formed through the partition member, a pathway is created upon the removal of the guidewire or other probe (for example, the closed cells are broken during advancement of the probe). Kranys discloses at column 2, lines 23-24, "In closed cell foams, the air in the cells has no way of escape, without breaking cell walls." Thus, it appears that the partition member of Kranys allows for the passage of air and in some instances fluids. Therefore, Kranys cannot be considered as teaching or suggesting, "the seal member does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen" as recited in claim 22.

Therefore, for at least these reasons, none of Matsumoto et al., Picha et al., or Kranys, taken alone or in combination, appear to teach or suggest the device as claimed. As such, the teachings of Matsumoto et al., Picha et al. and Kranys are not sufficient to render claim 22 *prima facie* obvious. For at least these reasons, claim 22 is believed to be patentable over Matsumoto et al., Picha et al., and Kranys and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 24-26, 28, and 30 which depend from claim 22 and include additional distinguishing features, are believed to be patentable over Matsumoto et al., Picha et al., and Kranys.

Claims 35 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. (U.S. Patent No. 4,610,665) in view of Picha et al. (U.S. Patent No. 5,080,654), Kranys (U.S. Patent No. 5,207,656), McClure (U.S. Patent No. 5,507,732), and Andrews et al. ("The Comparison of Commercial Getters"). Applicants respectfully traverse the rejection.

For similar reasons to those set forth above, as well as others, none of Matsumoto et al., Picha et al. or Kranys, taken alone or in combination, appear to teach or suggest "the seal does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within

the inflation lumen" as recited in claim Neither McClure nor Andrews et al. appear to remedy the noted shortcomings of Matsumoto et al., Picha et al. or Kranys. McClure appears to disclose seals including preformed openings which provide a friction fit with another component. McClure does not appear to teach or suggest a seal does not include a preformed opening and is self-sealing to maintain a vacuum as recited in claim 35. Andrews et al. appears to be directed towards "getters" and does not appear to teach or suggest presently claimed structure.

Therefore, for at least these reasons, none of Matsumoto et al., Picha et al., Kranys, McClure, or Andrews et al., taken alone or in combination, appear to teach or suggest the device as claimed. As such, the teachings of Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al. are not sufficient to render claim 35 *prima facie* obvious. For at least these reasons, claim 35 is believed to be patentable over Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al. and withdrawal of the rejection is respectfully requested. For similar reasons and others, claim 37 which depends from claim 35 and includes additional distinguishing features, is believed to be patentable over Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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/j. scot wickhem/

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